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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,874	11/21/2001	Wing L. Sung	07121.0003U1	2196
23859 7590 09/07/2007 NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			EXAMINER RAGHU, GANAPATHIRAM	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 09/07/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/990,874	Applicant(s) SUNG, WING L.	
	Examiner Ganapathirama Raghu	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,7,9,11-14,16-18,20-23,25-27,29-32,34-41,43-49 and 56-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 49 is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,7,9,11-14,16,18,20-23,25,27,29-32,34,37-41,43,44,46,48 and 56-71 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Application Status

Please note that the instant application/case has been transferred to examiner Ganapathirama Raghu, Art Unit 1652, whose telephone number is (571)-272-4533 and all further enquiries regarding this application should be directed to said examiner.

In response to the Office Action mailed on 12/21/2006, applicants' filed a response and amendment, received on 06/21/2007. Said amendment, amended claims 1 and 48 and canceled claims 3, 5, 8, 10, 15, 17, 19, 24, 26, 28, 33, 35, 42, 45, 47 and 50-55. Thus claims 1, 2, 4, 6, 7, 9, 11-14, 16, 18, 20-23, 25, 27, 29-32, 34, 37-41, 43, 48, 49 and 56-71 are pending in this application and are now under consideration.

Objections and rejections not reiterated from the previous action are hereby withdrawn.

Withdrawn-Claim Rejections: 35 USC § 102

Claims 1, 2, 4, 9 and 48 rejected under 35 U.S.C. 102(e) as being anticipated by Paloheimo et al., (U.S. patent No. 6,228,629) or Van Ooigen et al., (U.S. Patent No. 5,817,500) and claims 1, 2, 4, 9, 18, 48, 56 and 57 rejected under 35 U.S.C. 102(e) as being anticipated by Hansen et al., (U.S. Patent No. 5,817,500) are being withdrawn due to persuasive arguments by the applicant.

New-Claim Rejections: 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 recites the limitation in lines 5-6 "...wherein the modified Family 11 xylanase...". Claim 1 and claims 2, 4, 6, 7, 9, 11-14, 16, 18, 20-23, 25, 27, 29-32, 34, 37-41, 43, 48, 49 and 56-71, depending therefrom are rejected, as there is insufficient antecedent basis for

this limitation in the claim, as claim 1 in the preamble lacks reference to "modified Family 11 xylanase".

Maintained- Double Patenting rejection

Claims 1, 2, 4, 9 and 48 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6 and 34-42 of US Application No.: 11/37,644. Reasons for these rejections were explained in the previous office rejection letter dated 12/21/2006.

Applicants' have requested that this rejection be withdrawn, as upon review of the allowed claims, applicants' will consider filing a terminal disclaimer.

Reply: None of the claims are allowable at this stage of the prosecution and a terminal disclaimer has not as yet been filed. Therefore the rejections are maintained.

Maintained- Claim Rejections 35 USC § 112

Enablement

Claims 1-2, 4, 6, 7, 9, 11-14, 16, 18, 20-23, 25, 27, 29-32, 34, 37-41, 43, 44, 46, 48 and 56-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific variants of Family 11 xylanase of *Trichoderma reesei* consisting of a substitution at one or more positions as follows, a non-polar amino acid at position 116, a Cys at position 118, a basic amino acid at positions 144 and 161 of SEQ ID NO: 16, followed by modification of said variants at one or more other positions wherein said positions are limited to positions 10, 11, 27, 29, 75, 105, 125, 129 with specific amino acid residues, of SEQ ID NO:16, such that the modified xylanase continues to be classified in "Family 11" and continues to have thermophilic xylanase activity and a method of using said variant xylanase (claim 48) in pulp

manufacturing, does not reasonably provide enablement for any modified xylanase comprising at least one substitution selected from a non-polar amino acid at position 116, a Cys at position 118, a basic amino acid at positions 144 and 161 wherein said positions correspond to the amino acid positions in SEQ ID NO: 16. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In support of their request that said rejection be withdrawn, applicants' provide the following arguments:

(A) The person of ordinary skill in the art possesses significant knowledge and understanding of Family 11 xylanases, in addition applicants' have submitted concurrently a Declaration by Dr. T. White to provide clarification on what those skill in the art would understand from the prior art concerning Family 11 xylanases at the time the present invention was made.

(B) That the number of mutations that can be introduced into the amino acid sequence in claim 1 recites that the xylanase is a Family 11 xylanase exhibits activity against a xylan substrate and these features significantly reduce the number of variants encompassed by the claims.

These arguments are not found to be non-persuasive for the following reasons.

(A) & (B) Reply: First of all applicants' have construed that the amendments to claim 1 limits the claims only to Family 11 xylanase and the crux of the applicants' arguments are based on this conception. However, examiner would like to reiterate that the conception/belief of the applicant is not correct. Claim 1 as written when given the broadest interpretation reads on any

xylanase and is not limited to variants of Family 11 xylanase of *Trichoderma reesei* of SEQ ID NO: 16 having mutations at the recited positions. Furthermore, the breadth encompassed as a result of the phrase “comprising” (open language) allows any number of additional changes, even if claims were clearly limited to variants that are Family 11 xylanase enzymes. The requirements for inclusion in the Family 11 xylanase enzymes are so broad (as low as 48% homology), that claims still encompass number of variants and would be an undue burden to one skill in the art to make, identify variants with desired biological characteristics and use the variants for desired purposes. In addition, the specification has not provided structure-function relationship and tolerance of any modified xylanase to maintain the required configuration of the molecule and specific biological characteristics, especially for at least one or more of any non-polar amino acid, as non-polar amino acids comprise bulky amino acids like phenylalanine, tyrosine, tryptophan and helix breaking amino acid like proline. Therefore, the specification does not provide support for the scope and breadth of the claims.

Maintained-Written Description

Claims 1-2, 4, 7, 9, 12-14, 18, 21-23, 25, 27, 30-32, 34, 37, 39-41, 44, 46, 48 and 56-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In support of their request that said rejection be withdrawn, applicants’ have provided essentially the same argument that was presented to traverse the enablement rejection.. However, examiner maintains the rejection and the reason for the examiner’s position is given below.

Reply: Applicants' arguments are not persuasive as claim 1 as written is not limited to variants of Family 11 xylanase of *Trichoderma reesei* of SEQ ID NO: 16 nor to variants which must be Family 11 xylanases. They are drawn to any variant of a Family 11 xylanase having the recited features and thus the variant does not have to be a Family 11 xylanase. Thus the claimed proteins in claims 1-2, 4, 7, 9, 12-14, 18, 21-23, 25, 27, 30-32, 34, 37, 39-41, 44, 46, 48 and 56-71 can have any structure even structures with low percentage of similarity or even no similarity to SEQ ID NO: 16. The genus of polypeptides required in the claimed invention is an extremely large functionally variable genus. Many functionally unrelated polypeptides are encompassed by these claims with no structure-function correlation. Furthermore, that structurally related molecules may not possess similar function including desired binding specificity for substrates and enzyme kinetics and conversely functionally similar molecules may not share similar structural features or significant homology. The specification discloses only specific variants of Family 11 xylanase of *Trichoderma reesei* of SEQ ID NO: 16 of the recited genus, which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the required genus, especially variants with unknown sequence homology or very low sequence homology as said variants structure-function correlations are not disclosed. Therefore, given this lack of description of representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention. This rejection may be overcome by amending the claim to make clear that the mutant enzyme is a Family 11 xylanase.

Applicants are referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Summary of Pending Issues

The following is a summary of issues pending in the instant application.

- 1) Claim 1 and claims 2, 4, 6, 7, 9, 11-14, 16, 18, 20-23, 25, 27, 29-32, 34, 37-41, 43, 48, 49 and 56-71 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 2) Claims 1, 2, 4, 9 and 48 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6 and 34-42 of US Application No.: 11/37,644.
- 3) Claims 1-2, 4, 6, 7, 9, 11-14, 16, 18, 20-23, 25, 27, 29-32, 34, 37-41, 43, 44, 46, 48 and 56-71 are rejected under 35 U.S.C. 112, first paragraph for failing to comply with enablement.
- 4) Claims 1-2, 4, 7, 9, 12-14, 18, 21-23, 25, 27, 30-32, 34, 37, 39-41, 44, 46, 48 and 56-71 are rejected under 35 U.S.C. 112, first paragraph for failing to comply with written description requirement.
- 5) Claim 49 is found to be allowable.

Conclusion

Claims 1-2, 4, 6, 7, 9, 11-14, 18, 20-23, 25, 27, 29-32, 34, 37-41, 43, 44, 46, 48 and 56-71 are rejected/objected for the reasons identified in the Rejections and Summary sections of this

Office Action. Applicants must respond to the rejections in each of the sections in this Office Action to be fully responsive for prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached

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on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.

Patent Examiner

Art Unit 1652

August 27, 2007.

/Rebecca Prouty/

Primary Examiner

Art Unit 1652